

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

EVAN GEFNER and IVAN BABSIN on behalf of
themselves, all others similarly situated, and the
general public

Plaintiffs,

vs.

THE COCA-COLA COMPANY

Defendant.

Civil Action No. 17-cv-7952

**MEMORANDUM OF LAW IN SUPPORT OF THE COCA-COLA COMPANY'S
MOTION TO DISMISS THE COMPLAINT**

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PRELIMINARY STATEMENT

The Federal Food, Drug and Cosmetic Act (“FDCA”) establishes uniform definitions for terms that commonly appear on food labels throughout the United States. One such term is “diet,” which the statute and its implementing regulations define to mean “low calorie or reduced calorie.” In addition to dictating this general definition, the FDCA explicitly permits use of the term “diet” in the brand name of a low calorie soft drink.

This straightforward definition of “diet” is consistent with longstanding common usage of that term. Modern American dictionaries define “diet,” the adjective, as conveying “reduced in or free from calories,” and the term has been used for decades not only on Diet Coke, but on other low calorie soft drinks in Coca-Cola’s portfolio and throughout the beverage industry. Indeed, the ubiquity of “diet” soft drinks, and those products’ familiarity to consumers, is a primary reason that Congress expressly authorized use of the term “diet” to identify this category of low calorie products.

Plaintiffs Evan Geffner and Ivan Babsin nevertheless seek to impose a new definition of “diet,” and to prevent Coca-Cola from calling its iconic product “Diet Coke.” Plaintiffs do not dispute that Diet Coke is a zero calorie beverage that satisfies the prevailing definition of a “diet” soft drink. Rather, they allege that the use of the term “diet” leads consumers to believe that it will “contribute to healthy weight management” when, they allege, scientific studies call into question whether that is the case. Plaintiffs thus assert that Coca-Cola’s use of the term “diet” violates the FDCA’s broad prohibition on food label statements that are “false or misleading.” And because it purportedly breaches this overarching duty, Plaintiffs claim, the name “Diet Coke” also violates New York’s consumer protection laws and gives rise to various common law claims under New York law. On this basis, Plaintiffs seek, among other things, an injunction

requiring Coca-Cola to abandon its decades-old brand name.

Plaintiffs' outlandish request fails for two primary reasons. **First**, Plaintiffs' claims are preempted by federal law. In enacting the Nutrition Labeling and Education Act of 1990 ("NLEA"), Congress determined that it was essential that food labels be uniform throughout the Nation, and that state and local authorities not impose labeling standards or definitions that differ from federal requirements. To that end, Congress empowered a single federal agency, the U.S. Food and Drug Administration ("FDA"), to adopt uniform definitions of common food labeling terms. And it expressly preempted individual states, including courts acting under color of state law, from imposing food-labeling requirements that are not *identical* to most federal requirements. Where, as here, the FDCA provides a uniform definition for a term such as "diet," a private litigant may not seek to utilize state law to assert that the use of the term is "false or misleading."

Second, Plaintiffs cannot hold Coca-Cola accountable for a promise of "weight management" that it never made. The brand name Diet Coke accurately conveys that the product is low in calories, consistent with the dictionary definition and FDCA usage of the term "diet." The "misleading" message that Plaintiffs claim to have taken from the brand name—that the sheer act of drinking Diet Coke contributes to "healthy weight management"—can be found nowhere on Diet Coke's label or advertising. Indeed, a virtually identical class action, also relating to Diet Coke and filed by Plaintiffs' counsel, has already been dismissed on this basis. In that case, which Plaintiffs' counsel filed in the Northern District of California the day they filed this one, the court concluded that the plaintiff had not plausibly alleged that Diet Coke conveys a misleading "weight management" message to reasonable consumers. The same deficiency dooms Plaintiffs' claims in this case.

Plaintiffs' statutory consumer protection claims are also barred by the relevant statutes' safe harbor provisions, which provide a "complete defense" to claims challenging conduct that is "subject to and complies with the rules and regulations" of any federal agency, including FDA. Furthermore, Plaintiffs lack standing to seek injunctive relief, and their common law claims fail as a matter of law for a variety of reasons. The complaint should be dismissed in its entirety.

BACKGROUND

A. The FDCA Preempts Most State Labeling Requirements That Are Not Identical To Federal Law

In 1990, Congress passed the NLEA "to 'clarify and strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods.'" *Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 223 (2d Cir. 1998) (quoting H.R. Rep. No. 101-538, at 7 (1990)). In enacting the NLEA, Congress sought to establish "consistent, enforceable rules pertaining to the claims that may be made with respect to the benefits of nutrients in foods." H.R. No. 101-538, at 7-8 (1990). Uniform nationwide rules, Congress determined, would help consumers "make sense of the confusing array of nutrition labels that confront [them] every time they enter the supermarket." 136 Cong. Rec. H5836-01 (July 30, 1990) (statement of Rep. Waxman).

In order to ensure the rules' uniformity, Congress deemed it necessary to "prevent state and local governments from adopting inconsistent requirements ... with respect to the claims that may be made about nutrients in foods." H.R. No. 101-538, at 8. Congress did not act lightly in forcing states out of the business of food-label regulation. Rather, it authorized FDA to commission the U.S. Institute of Medicine to study the issue in depth and catalogue the various state laws that the FDCA would displace. *See* Institute of Medicine, *Food Labeling: Toward*

National Uniformity, National Academy Press (Washington D.C. 1992). Ultimately, Congress concluded that preempting inconsistent state requirements would be “fair to both consumers and industry,” because a uniform interstate scheme would require “disclosure of all valid and relevant information to the consumer, while providing the industry with uniformity of law ... that will permit them to conduct their business of food distribution in an efficient and cost-effective manner.” *See* 136 Cong. Rec. H5836-01 (July 30, 1990) (statement of Rep. Madigan); *see also* 136 Cong. Rec. S16607 (Oct. 24, 1990) (“It is wrong to permit each of the 50 States to require manufacturers ... to display different health and diet information on identical products sold throughout this country.”) (statement of Sen. Hatch).

In accordance with this goal, the FDCA provides that no state “may directly or indirectly establish ... any requirement ... that is *not identical* to the requirement[s]” of various food-labeling provisions of the statute. 21 U.S.C. § 343-1(a)(1)-(5) (emphasis added). A state requirement is preempted if it “imposes obligations” that “[d]iffer from those *specifically imposed* by or contained in the applicable provision (including any implementing regulation).” 21 C.F.R. § 100.1(c)(4) (emphasis added). “Thus, state law cannot impose obligations beyond, or different from, what federal law requires.” *In re Pepsico, Inc.*, 588 F. Supp. 2d 527, 532 (S.D.N.Y. 2008). This federal preemption scheme reflects Congress’s considered judgment that “the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result.” 58 Fed. Reg. 2462, 2462 (Jan. 6, 1993).

B. Federal Law Authorizes Use of the Word “Diet” on the Label of Diet Coke

Both the FDCA itself and its implementing regulations authorize use of the term “diet” on low calorie soft drinks such as Diet Coke. The statute provides that low calorie soft drinks marketed prior to 1989 (as was Diet Coke) may continue to use the term “diet” in their brand names, so long as they satisfied the FDA regulation applicable to “diet” claims in force at that

time. Current FDA regulations, meanwhile, provide that a soft drink marketed after 1989 may be labeled as “diet” if it satisfies the present-day regulation governing use of that term. While there are some differences between the pre-1989 regulation and the current one, the definition of “diet” has not changed: FDA has consistently defined the term to refer to a food with low or reduced calorie content. Because it meets this simple standard, Diet Coke is properly labeled as “diet” under federal law.

1. Low Calorie Soft Drinks Marketed Prior to 1989

FDA first defined the term “diet” in 1978, more than a decade before the NLEA was enacted. It did so after finding that a “common standard” for such label designations could assist consumers in managing their dietary intake. *See* 43 Fed. Reg. 43248, 43257 (Sept. 22, 1978). To achieve this objective, FDA adopted a straightforward definition of “diet” as “suggesting usefulness as [a] low calorie or reduced calorie food[],” and imposed clear standards for the latter two terms. 21 C.F.R. § 105.66(c), (d), (e) (1978).¹ It then authorized use of the term “diet” on products that qualified as “low calorie” or “reduced calorie” and were labeled as such. *Id.* This regulation was in effect when, in 1982, Coca-Cola introduced Diet Coke, the low calorie analogue to its flagship cola product. (*See* Compl. ¶ 1.) Other low calorie soft drinks branded as “diet” soon followed.

By the time the NLEA amendments were enacted in 1990, “diet” had become so ubiquitous on low calorie soft drinks that Congress specifically addressed the term in Section 343(r), the FDCA provision governing “nutrient content” claims. Although Section 343(r) generally proscribes “nutrient content” claims using terms that are not defined by FDA regulations, Section 343(r)(2)(D) provides that, subject to the general prohibition on false or

¹ At that time, FDA regulations permitted a food to be identified as “low calorie” if it contained fewer than 40 calories per serving and 0.4 calories per gram. *See* 21 C.F.R. § 105.66(c) (1978).

misleading labeling, the use of the term “diet” on a soft drink is exempt from that default “nutrient content claim” proscription if (1) the term is part of the product’s brand name; (2) that brand name was in use prior to October 25, 1989; and (3) “the use of the term ‘diet’ *was* in conformity with section 105.66”—the regulation defining “diet”—at that time. 21 U.S.C. § 343(r)(2)(D) (emphasis added). Congress thus provided that, while FDA might change the regulatory definition of “diet” in the future, pre-1989 soft drinks whose labels complied with the 1989 definition were “grandfathered” and could continue to use the term. At the same time, Congress gave preemptive effect to Section 343(r). 21 U.S.C. §§ 343(r); 343-1(a)(5).

The context of the “grandfathering” provision makes clear that it was specifically intended to codify FDA’s original definition of “diet” for pre-1989 soft drinks. Section 343(r)(2)(D) immediately follows a parallel provision that—again subject to the general prohibition on false or misleading labeling—authorizes any claim relating to nutrient content that is part of a product’s brand name where (1) the name was in use before October 25, 1989; and (2) it does not “use[] terms which are defined in the regulations of the [FDA].” 21 U.S.C. §§ 343(r)(2)(C), 343(r)(2)(A)(i). This provision did not cover Diet Coke because “diet” had already been defined by FDA regulation as “suggesting usefulness as [a] low calorie or reduced calorie food[.]” 21 C.F.R. § 105.66(e) (1978). Congress’s decision to adopt a separate “grandfathering” provision for diet soft drinks, and to reference FDA’s then-current definition of “diet” in that provision, reflects its approval of that definition when used on soft drinks.

The reference in Section 343(r)(2)(D) to the FDCA’s general prohibition on “false or misleading” labeling does not undermine or weaken that endorsement, but simply provides a safeguard against improper manipulation of the “grandfathering” scheme. *See* 21 U.S.C. § 343(r)(2)(D) (providing that “diet” claims on soft drinks are “subject to paragraph [343](a)”; §

343(a) (prohibiting food labels that are “false or misleading in any particular”). Section 343(r)(2)(D) permits use of the term “diet” on any soft drink whose label “was in conformity” with the FDA definition *as of 1989*. The current FDA regulation implementing the provision likewise provides that any “diet” soft drink marketed before October 25, 1989 is subject to an “exemption[]” from the default rules regarding nutrient content claims, such that it “*may continue* to use that term as part of its brand name” provided that its “use of that term was in compliance with § 105.66 . . . *on that date*.” 21 C.F.R. § 101.13(q)(2) (emphases added). Accordingly, absent the general prohibition on “false or misleading” labeling, these provisions could be read to permit such a beverage to retain the “diet” name indefinitely, even if its calorie content increased and it ceased to qualify as a low or reduced calorie product. Section 343(r)(2)(D)’s incorporation of Section 343(a) prevents manufacturers from engaging in that manipulation.

2. Low Calorie Soft Drinks and Foods Marketed After 1989

Although Section 343(r)(2)(D) made FDA’s original definition of “diet” permanently applicable to pre-1989 diet soft drinks irrespective of subsequent changes to the definition, no such changes have actually been adopted. After passage of the NLEA amendments, FDA issued numerous new regulations, including a revised version of Section 105.66—but left its longstanding definition of “diet” undisturbed. The amended Section 105.66, issued in 1993, continues to define “diet” as a term “suggesting usefulness as [a] low calorie or reduced calorie food[].” 21 C.F.R. § 105.66(e).² FDA’s decision to re-affirm its definition of “diet” after

² FDA did, however, make minor revisions to the underlying definitions of “low calorie” and “reduced calorie” in the 1993 amendments. Under current FDA regulations, a food qualifies as “low calorie” if it (1) has a “reference amount customarily consumed” of greater than 30 grams; and (2) it does not provide more than 40 calories per reference amount customarily consumed. See 21 C.F.R. §§ 105.66(c), 101.60(b)(2).

passage of the NLEA was the result of careful consideration. The agency explained in a 1991 Notice of Proposed Rulemaking that its original definition “provide[d] for the term ‘diet’ for use when a food is represented as being *useful in reducing caloric intake* or maintaining body weight,” and that the term “ha[d] often been used on foods that are virtually free of calories, such as specially formulated soft drinks.” 56 Fed. Reg. 60421, 60438 (Nov. 27, 1991) (emphasis added). Aware of this widespread use, FDA opted for continuity with respect to the term. Responding to a request for guidance from the soft drink industry regarding post-NLEA standards, it explained that “the agency [was] continuing to define the term ‘diet’ in its regulation, specifically in § 105.66,” and that soft drinks introduced after 1989 could use the term so long as they were “in conformity with” that definition. 58 Fed. Reg. 2302, 2313 (Jan. 6, 1993). FDA further noted that all diet soft drinks then on the market—of which Diet Coke was the most prominent example—met that standard. It expressly stated that it was unaware of “any instances whereby line extensions for ‘diet’ soft drinks would not be in conformity with § 105.66.” *Id.*

The updated version of Section 105.66 did reflect some revisions from the prior version, including a proviso that terms such as “diet” could not be used if they were false or misleading. 21 C.F.R. § 105.66(e). But once again, this proviso simply prohibits foods that do not satisfy the definition of “diet” from being labeled as though they do. FDA made that purpose clear when promulgating the regulation. Using formulated meal replacements (another product governed by Section 105.66) as an example, FDA explained that “*if a food that is not a formulated meal replacement purported on its label to be a formulated meal replacement* ... FDA would consider the food to be [improperly labeled].” It then clarified that the new proviso would permit FDA “to *take action against any food that uses terms such as ‘diet’ ... in this manner.*”

58 Fed. Reg. 2427, 2428 (Jan. 6, 1993) (emphases added). Accordingly, as in Section 343(r)(2)(D), the qualifier regarding “false or misleading” claims complements the definition of “diet” by limiting the term’s use to products that actually satisfy the regulatory definition.

3. Application to Diet Coke

Section 343(r)(2)(D) of the FDCA authorizes the term “diet” for pre-1989 low calorie soft drinks. At the same time, FDA regulations specify that (1) pre-1989 soft drinks “may continue” to use the term “diet” if, on October 25, 1989, their labels complied with Section 105.66 “as that regulation appeared in the Code of Federal Regulations *on that date*”; and (2) soft drinks “marketed after October 25, 1989 may use the term ... provided they are in compliance with the *current* [Section] 105.66 of this chapter.” 21 C.F.R. § 101.13(q)(2) (emphases added).

Each of these provisions constitutes a separate and independent authorization of Diet Coke’s brand name. At the time Section 343(r)(2)(D) was enacted, Diet Coke had been on the market for seven years. Then, as now, Diet Coke contained zero calories per serving, and in accordance with the requirements of Section 105.66, was labeled as low calorie. *See* Declaration of Jane Metcalf (“Metcalf Decl.”) Ex. 1; *see also* 21 C.F.R. § 105.66(c), (e) (1978).³ Diet Coke also complied with the separate regulatory requirement that all foods using the term “diet” include on their labels certain general nutritional information. *See* 21 C.F.R. § 105.66(a) (1978). Diet Coke’s use of “diet” in its brand name is thus permitted under the “grandfathering” provision of Section 343(r)(2)(D) and its implementing regulation.

Diet Coke’s brand name is also permitted by 21 C.F.R. § 101.13(q)(2), which provides

³ Documents or materials “incorporated in the complaint by reference” or “upon which the complaint relies and which are integral to the complaint” may be properly considered on a motion to dismiss. *Subaru Distribs. Corp. v. Subaru of Am., Inc.*, 425 F.3d 119, 122 (2d Cir. 2005).

for use of the term “diet” on post-1989 soft drinks that comply with the current requirements of Section 105.66. Those requirements are substantially the same as the ones that applied in 1989, and Diet Coke’s current label complies with them. *See* Metcalf Decl., Ex. 1; *see also* 21 C.F.R. § 105.66(e).

C. Plaintiffs’ Allegations

Plaintiffs do not allege that Diet Coke fails to satisfy FDA’s definition of “diet” as “low calorie or reduced calorie.” Rather, they contend that the FDCA’s general prohibition on “false or misleading” label statements gives private litigants like themselves carte blanche to impose a new definition of that term.

Plaintiffs claim that Coca-Cola’s use of the term “diet” suggests not only that Diet Coke is low in calories, but that it will, in some unspecified manner, “assist in weight loss” or at least “contribute to healthy weight management.” (Compl. ¶¶ 14, 49) They maintain that the label’s implicit message regarding “weight management” is false because—according to their interpretation of the available scientific evidence—artificial sweeteners such as aspartame “interfere with the body’s ability to properly metabolize calories” and may “lead[] to weight gain and increased risk of metabolic disease, diabetes, and cardiovascular disease.” (Compl. ¶ 2) Plaintiffs thus ask the Court to disregard the definition of “diet” embraced by both FDA and by modern English dictionaries, and to find that the name Diet Coke is false or misleading because it does not live up to their understanding of what a “diet” beverage should be.⁴

One district court has already rejected this argument. In *Becerra v. Coca-Cola Co.*, 17-

⁴ The same day this case was filed, counsel for plaintiffs also filed complaints in this Court against Pepsico and Dr. Pepper Snapple Group, asserting substantially similar claims in connection with those companies’ diet soft drinks. *See Manuel, et al. v. Pepsi-Cola Company*, 17-cv-7955 (S.D.N.Y.) (filed Oct. 16, 2017); *Excevarria, et al. v. Dr. Pepper Snapple Group, Inc., et al.*, 17-cv-7957 (S.D.N.Y.) (filed Oct. 16, 2017).

cv-5916 (N.D. Cal.) (filed Oct. 16, 2017), Plaintiffs’ counsel represented a California consumer asserting virtually identical claims on behalf of a putative class of California Diet Coke purchasers. On February 27, 2018, the court (Alsup, *J.*) granted Coca-Cola’s motion to dismiss the complaint on the ground that the plaintiff had not plausibly alleged that Diet Coke’s brand name was misleading to reasonable consumers. Although the court concluded, after a brief discussion in dicta, that the plaintiff’s claims were not preempted, it held that her consumer protection claims failed because she had not credibly alleged that “a reasonable consumer would simply . . . look at the brand name Diet Coke and assume that consuming it . . . would lead to weight loss.” *Becerra v. Coca-Cola Co.*, 2018 U.S. Dist. LEXIS 31870, at *8 (N.D. Cal. Feb. 27, 2018).

The *Becerra* court’s reasoning on that dispositive issue applies with equal force here. Reasonable consumers interpret the word “diet,” consistent with its popular and FDA definitions, to convey that Diet Coke is low in calories, not that it is epidemiologically linked to weight loss. Plaintiffs cannot plausibly allege otherwise. Plaintiffs also cannot credibly allege that Diet Coke is, in fact, linked to weight gain; on the contrary, every one of the studies they cite cautions *against* that conclusion, and a few express outright skepticism of any causal connection.⁵

⁵ See, e.g., Sharon P. Fowler et al., *Fueling the Obesity Epidemic? Artificially Sweetened Beverage Use and Long-Term Weight Gain*, Obesity, Vol. 16, No. 8, 1894-1900 (Aug. 2008) (noting that increased reliance on diet soft drinks by “individuals already on weight-gain trajectories” was “the most obvious possible explanation” for possible correlation between diet soft drink consumption and weight gain) (cited at Compl. ¶ 25 and n.7); Rebecca J. Brown et al., *Artificial Sweeteners: A Systematic Review of Metabolic Effects in Youth*, Int’l J. of Ped. Obesity, Vol. 5, No. 4, 305-12 (Aug. 2010) (noting that “the jury remains out regarding a possible role of increased artificial sweetener use” in the increased prevalence of obesity and diabetes) (cited at Compl. ¶ 19 and n.2); see also Richard D. Mattes and Barry M. Popkin, *Nonnutritive Sweetener Consumption in Humans: Effects on Appetite and Food Intake and Their Putative Mechanisms*, Am. J. Clin. Nutr., Vol. 89, No. 1, 1-14 (Jan. 2009) (observing that “intervention trials consistently fail to document that [artificial sweeteners] promote weight gain, and observational studies provide only equivocal evidence that they might”) (cited at Compl. ¶

Accordingly, Plaintiffs' complaint should be dismissed not only because it is preempted, but also because it fails to allege conduct that would mislead a reasonable consumer, as New York consumer protection law requires.

ARGUMENT

To avoid dismissal under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice"; instead, the plaintiff must "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Where a complaint contains only state-law claims that are expressly preempted by federal law, the complaint must be dismissed in its entirety. *See, e.g., In re PepsiCo, Inc.*, 588 F. Supp. 2d 527, 538–39 (S.D.N.Y. 2008).

Here, Plaintiffs' claims are expressly preempted by the FDCA, and the complaint fails to state a claim for any of the asserted causes of action. In addition, Plaintiffs lack standing to seek injunctive relief. Accordingly, their complaint should be dismissed.

I. ALL OF PLAINTIFFS' CLAIMS ARE EXPRESSLY PREEMPTED

A. Plaintiffs' Claims Seek to Impose Requirements That Are Not Identical to Federal Law

Diet Coke's label is authorized by the FDCA and its implementing regulations because (1) the product satisfied the definition of "diet" in 1989 and (2) it satisfies that definition today. *See* 21 U.S.C. § 343(r)(2)(D); 21 C.F.R. §§ 101.13(q)(2), 105.66(e). Plaintiffs, however, seek to

18 and n.1); Meghan B. Azad et al., *Nonnutritive sweeteners and cardiometabolic health: a systematic review and meta-analysis of randomized controlled trials and prospective cohort studies*, Can. Med. Ass'n J., Vol. 189, No. 28, 929-39 (July 2017) (noting "limited evidence for the effect of [artificial] sweeteners on BMI.") (cited at Compl. ¶ 28 and n. 10). *See* Metcalf Decl. Exs. 2-5.

use New York law to impose additional requirements for the use of the term. They maintain that Diet Coke may be labeled as “diet” only if they are satisfied that its consumption will contribute to “healthy weight management.” (Compl. ¶ 49)

Plaintiffs’ claims are expressly preempted. “Express preemption is present when Congress’s intent to preempt state law is explicitly stated in the statute’s language.” *In re PepsiCo*, 588 F. Supp. 2d at 530 (internal quotation marks omitted). Here, the FDCA explicitly “preempts any state law that imposes a requirement ‘that is different from or in addition to, or that is otherwise not identical with’ a requirement of the FDCA” or its implementing regulations. *O’Connor v. Henkel Corp.*, 2015 U.S. Dist. LEXIS 140934, at *11 (E.D.N.Y. Sep. 21, 2015); 21 U.S.C. § 343-1(a). Accordingly, private plaintiffs may not use state law to “impose a burden ... that is not identical to the[se] requirements.” *Carrea v. Dreyer’s Grand Ice Cream, Inc.*, 475 Fed. App’x. 113, 115 (9th Cir. 2012). Rather, state-law claims arising from the labeling of food are limited to those “seek[ing] to impose requirements that (1) are identical to those imposed by the FDCA, or (2) are outside the scope of the relevant federal requirements.” *O’Connor*, 2015 U.S. Dist. LEXIS 140934, at *11.

Neither of these is the case here. Diet Coke’s brand name, which is explicitly addressed by both Section 343(r), the FDCA section pertaining to “nutrient content” claims, and 21 C.F.R. § 101.13, which implements that section through regulation, 21 U.S.C. § 343(r)(2)(D); 21 C.F.R. § 101.13(q)(2), falls squarely within the “scope of relevant federal requirements.” *O’Connor*, 2015 U.S. Dist. LEXIS 140934, at *11. Those sections set forth discrete criteria for the use of the term “diet” on a soft drink, and Diet Coke satisfies every one of them. Plaintiffs, however, seek to impose a new requirement—that Diet Coke comport with their views regarding weight management—which is *not* “identical to those imposed by the FDCA.” *Id.* In other words, they

“seek[] to enjoin and declare unlawful the very statement that federal law permits and defines.” *Carrea*, 475 Fed. App’x. at 115. Their claims are thus preempted.

Courts routinely dismiss similar complaints on this basis. In *In re Pepsico, Inc.*, 588 F. Supp. 2d 527 (S.D.N.Y. 2008), for example, the plaintiffs alleged that defendant’s labeling of its “purified drinking water” was misleading under state law because defendant did not disclose that the water was sourced from a public water supply rather than from a mountain spring. The court rejected this argument, noting that a specific FDA regulation governed the labeling for purified water, and that “state law cannot impose obligations beyond, or different from, what federal law requires.” *Id.* at 532 (citing 21 C.F.R. § 100.1(c)(4)(i)-(ii)). It accordingly held that the plaintiffs’ claims, which sought to “impose requirements in addition, and not identical, to federal requirements,” were “preempted under . . . the FDCA.” *Id.* at 537; *see also Bimont v. Unilever U.S., Inc.*, 2015 U.S. Dist. LEXIS 119908, at *16 (S.D.N.Y. Sep. 9, 2015) (finding plaintiffs’ claims preempted because they sought to “impose a requirement that is in addition to or not identical with federal law” regarding “subject matter that clearly could be regulated by the FDA”); *Samet v. P&G*, 2013 U.S. Dist. LEXIS 86432, at *20 (N.D. Cal. June 18, 2013) (“Express preemption is especially appropriate where the practice identified by the plaintiff is explicitly governed by either the FDCA or its regulations, and the defendant is in compliance with those requirements”). The result can be no different here.

Indeed, the FDCA’s preemption clause bars even challenges to claims that are alleged to be literally false. *See Guttman v. Nissin Foods (U.S.A.) Co.*, 2015 U.S. Dist. LEXIS 92756 (N.D. Cal. July 15, 2015), at *9 (dismissing complaint challenging a manufacturer’s use of the claim “0g Trans Fat” on a product containing a small amount of trans fat). Here, Plaintiffs’ assertion that Diet Coke’s label is “misleading” rests on their interpretation of tentative and

contradictory scientific evidence: as noted in one of the studies they cite, “the jury remains out” on the question of a relationship between diet soft drink consumption and weight gain.⁶ If private plaintiffs were permitted to use state law to rewrite food-labeling rules on the basis of such nascent scientific theories, those rules would be subject to constant change and confusing interstate variation, as differing courts arrived at differing interpretations of the science. This would sabotage Congress’s overarching goal of “uniformity of law ... [to] permit [manufacturers] to conduct their business of food distribution in an efficient and cost-effective manner.” *See* 136 Cong. Rec. H5836-01 (July 30, 1990) (statement of Rep. Madigan).

B. Plaintiffs Cannot Use the FDCA Prohibition on “False or Misleading” Claims As An End-Run Around Its Preemptive Effect

Plaintiffs maintain that although Diet Coke’s label complies with the requirements of Section 343(r)(2)(D) and corresponding regulations, it is nevertheless actionable under state law because it violates the statute’s catch-all prohibition on “false or misleading” claims, which is incorporated by reference in Section 343(r)(2)(D). Accordingly, they argue, their state-law claim merely seeks to impose “parallel” requirements to those of the FDCA, not to encroach on them with contradictory state-law requirements.

Plaintiffs are wrong. Courts have consistently rejected efforts, like this one, to use the FDCA’s general prohibition on “false or misleading” claims as a vehicle for imposing additional requirements on claims governed by more specific provisions—even where, as here, the latter incorporate the former. In *Red v. Kroger Co.*, 2010 U.S. Dist. LEXIS 115238 (C.D. Cal. Sept. 2, 2010), for example, the plaintiff asserted that the defendant’s “cholesterol free” claim violated

⁶ Rebecca J. Brown et al., *Artificial Sweeteners: A Systematic Review of Metabolic Effects in Youth*, Int’l J. of Ped. Obesity, Vol. 5, No. 4, 305-12 (Aug. 2010) (noting that “the jury remains out regarding a possible role of increased artificial sweetener use in the obesity and diabetes epidemics”) (cited at Compl. ¶ 19 n.2); *see* Metcalf Decl. Ex. 3.

not only the catch-all Section 343(a) prohibition on “false or misleading” labeling, but also the regulation governing “nutrient content” claims, which—like the provisions at issue here—both set forth specific requirements for such claims *and* expressly incorporated the general proviso that they could not be “false or misleading.” *See id.* at *10-11 (citing 21 C.F.R. § 101.13(i)(3)). There, as here, the plaintiffs argued that their claim was not preempted because they simply sought to enforce that general prohibition. And there, as here, no FDCA provision *required* the product in question to be labeled “No Cholesterol,” so the plaintiffs’ claim did not threaten to subject the manufacturer to actively inconsistent requirements.

Nevertheless, the court found the suit preempted. It reasoned that the manufacturer’s compliance with specific provisions addressing the term in question “directly undermine[d] Plaintiff’s argument that Defendant’s use of [the term] [wa]s ‘false and misleading’” under the more general prohibition. *Id.* at *13. As the court explained:

Given that federal regulations specify when the term[] “cholesterol free” can be used, Defendant’s compliance with those regulations cannot be deemed to be “false and misleading.” ... While both 21 U.S.C. § 343(a) and 21 C.F.R. § 101.13(i)(3) prohibit labels from being “false or misleading” or from characterizing nutrient levels in a “false or misleading” way, **21 U.S.C. § 343(r) and accompanying regulations describe, in detail, nutrient content claims that are permitted under federal law and, therefore, by definition, are not considered “false or misleading” under federal law.**

Id. at *13-15 (emphasis added). Numerous other courts have reached the same conclusion. *See In re PepsiCo, Inc.*, 588 F. Supp. 2d at 532 (holding that “state law cannot impose obligations beyond, or different from, what federal law requires”); *Yumul v. Smart Balance, Inc.*, 2011 U.S. Dist. LEXIS 109952, at *32-33 (C.D. Cal. Mar. 14, 2011) (holding that where challenged terms “are either expressly defined or permitted under federal regulations, the Court must reject [the] argument that nutrient content claims using those same terms in a regulation-compliant manner are nonetheless ‘false and misleading’”) (internal quotation marks and citations omitted);

Gorenstein v. Ocean Spray Cranberries, Inc., 2010 U.S. Dist. LEXIS 143801, at *1, *4 (C.D. Cal. Jan. 29, 2010) (rejecting plaintiff’s reliance on Section 343(a) where defendant’s description of its juice “complie[d] with all requirements of federal law.”); *Coe v. Gen. Mills*, 2016 U.S. Dist. LEXIS 105769, at *11 (N.D. Cal. Aug. 10, 2016) (“[A] statement cannot be ‘false or misleading’ under Section 343(a) ‘where [the] challenged conduct is expressly ... permitted by FDA regulations.’”).

Here too, the FDCA “describe[s], in detail” when the term “diet” is permitted on soft drinks, and thus “by definition” is not false or misleading under federal law. *Red v. Kroger Co.*, 2010 U.S. Dist. LEXIS 115238, at *15. Plaintiffs cannot use the “false or misleading” prohibition to circumvent the preemptive effect of the Section 343(r) provisions that “expressly define[] or permit[]” the precise claim at issue. *Yumul*, 2011 U.S. Dist. LEXIS 109952, at *33.

The fact that Diet Coke’s label is under “*no requirement* to use the term ‘diet,’” and therefore at no risk of becoming subject to “incompatib[le]” requirements should Plaintiffs’ claims proceed, does not change this analysis. *Becerra*, 2018 U.S. Dist. LEXIS 31870, at *7. In determining whether a state-law claim is preempted by the FDCA, “[t]he standard ... is not whether a state law actively undermines federal law. It is whether state law diverges from federal law *at all*.” *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 375 (S.D.N.Y. 2014) (emphasis added); *see also Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 427 (7th Cir. 2011) (“[C]onsistency is not the test; identity is.”). In other words, “[w]here federal law *specifically regulates* the subject matter of a plaintiff’s state law claims, and those claims seek to impose requirements not identical to federal requirements, those state law claims are preempted.” *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d, 312, 320 (S.D.N.Y. 2017) (emphasis added). Here, because federal law “specifically regulates” the subject matter at issue, *id.*, Plaintiffs

cannot use state law to impose different requirements—even ones that are purportedly consistent with, or complementary to, federal standards.

C. Section 343(r) and FDA Regulations Impose Clear Conditions on the Term “Diet” in Soft Drink Brand Names

Finally, Plaintiffs seek to overcome this principle by asserting that the requirements for diet soft drink brand names imposed by Section 343(r)(2)(D) and its implementing regulations are not really preemptive “requirements” at all, but an exceedingly roundabout way of leaving “diet” soft drinks ungoverned by any provision other than the general prohibition on “false or misleading” claims. This argument is spurious.

Plaintiffs seize upon the fact that Section 343(r)(2)(D) is drafted in the negative: it provides that Section 343(r)’s restrictive scheme, which generally prohibits the use of “nutrient content” claims, “does not apply to a claim” that satisfies the three criteria delineated in Section 343(r)(2)(D). To the extent it contains affirmative language, Plaintiffs note, Section 343(r)(2)(D) states only that “[s]uch a claim is subject to paragraph (a),” the general prohibition on false or misleading label statements. Plaintiffs thus argue that the net effect of Section 343(r)(2)(D) is to leave “diet” soft drink claims subject *only* to that general prohibition—*i.e.*, to leave those claims in the same position they would be if Section 343(r) did not exist at all. The *Becerra* court embraced this position in dicta, concluding that Section 343(r)(2)(D) “does not positively authorize” the use of the term “diet,” but instead sets forth conditions under which Section 343(a), rather than Section 343(r), applies.

This reading of the statute is incorrect for several reasons. *First*, in the context of Section 343(r), the “exception” language of Section 343(r)(2)(D) *is* a “positive authorization,” because the function of Section 343(r)(2)(D) is to exempt “diet” soft drink claims from the restrictions imposed by Section 343(r). Section 343(r) establishes a default principle that a food label may

not “characterize[] the level of any nutrient” in a food unless “the characterization of the level made in the claim uses terms which are defined in regulations of [FDA].” 21 U.S.C. §§ 343(r)(1)(A), (r)(2)(A)(i). But under Section 343(r)(2)(D), “the term ‘diet’ . . . contained in the label or labeling of a soft drink” is an exception to that general rule, so long as the provision’s detailed criteria are met. 21 U.S.C. § 343(r)(2)(D). In that case, the term “diet” *is* permissible, irrespective of the content of FDA regulations, “subject to” the general prohibition on false or misleading statements.

This use of a double negative to create a positive authorization, reader-unfriendly though it may be, is endemic to the FDCA. By its terms the statute does not “expressly authorize” *any* food-labeling claim, but simply declares that “[a] food shall be deemed to be misbranded” whenever enumerated circumstances are *not* met (*e.g.*, “[u]nless its label bears . . . the common or usual name of the food” and “the common or usual name of each . . . ingredient” therein, 21 U.S.C. § 343(i)). Yet these enumerated circumstances, as courts have repeatedly held, “describe . . . claims that *are permitted under federal law*,” because food labels that comply with them are not deemed to be misbranded. *Red*, 2010 U.S. Dist. LEXIS 115238, at *15 (emphasis added). The same principle applies here: by specifying that a “diet” soft drink meeting its criteria is *not* subject to the default prohibition of Section 343(r), Section 343(r)(2)(D) provides an express statutory permission for such a claim. *Id.*, *see also* 21 U.S.C. § 343(r)(2)(D). Plaintiffs cannot use state law to impose additional conditions on that permission.

Second, Plaintiffs’ interpretation has been rejected by FDA, whose regulations make clear that it reads Section 343(r) to create an express statutory authorization for pre-1989 “diet” soft drinks. These regulations provide that a soft drink that used the term as part of its brand name before October 25, 1989, and whose use of the term complied with FDA regulations on

that date, “*may continue to use that term* as part of its brand name,” subject to the general prohibition on false or misleading statements. *See* 21 C.F.R. § 101.13(q)(2) (emphasis added). Notably, this provision, like Section 343(r)(2)(D), is framed as an “exemption” from the general principle that claims about nutrient content “may not be made”—further underscoring that both provisions in fact provide “positive authorization” for Diet Coke’s brand name. *See* 21 C.F.R. §§ 101.13(q), 101.13(b).

Finally, Plaintiffs’ tortured interpretation of Section 343(r)(2)(D), if correct, would lead to the absurd result that older soft drinks are vulnerable to private suit while newer ones are not. Under Plaintiffs’ reading, the effect of Section 343(r)(2)(D) is to remove soft drinks satisfying its criteria from the purview of Section 343(r), leaving them subject only to the residual requirement of Section 343(a). But for diet soft drinks that do *not* satisfy those requirements—such as those introduced after October 25, 1989—Plaintiffs have not disputed that the default scheme of Section 343(r) applies. And as Plaintiffs have also not disputed, that default scheme permits use of the word “diet” on low calorie soft drinks, because it is “defined in regulations” of FDA as a “label term[] suggesting usefulness as [a] low calorie or reduced calorie food[.]” 21 U.S.C. § 343(r); 21 C.F.R. § 105.66(e). In addition, a separate FDA regulation expressly authorizes its use on “[s]oft drinks marketed after October 25, 1989.” 21 C.F.R. § 101.13(q)(2). So according to Plaintiffs’ reading, a “diet” soft drink introduced prior to October 25, 1989 is subject only to the “false or misleading” proviso in Section 343(a), but a “diet” soft drink introduced one day later is governed, and permitted, by Section 343(r) and its implementing regulations. Congress could not have intended such a preposterous result.

This Court should reject Plaintiffs’ reading of Section 343(r)(2)(D), and conclude that that provision, like every other provision in Section 343(r), imposes positive criteria for use of

the term “diet” in soft drink brand names. These criteria cannot be displaced, added to, or modified by state law.

D. Plaintiffs May Not Use 21 C.F.R. § 1.21(a), Another General Provision, to Evade FDCA Preemption

Plaintiffs’ alternative suggestion that Diet Coke’s label violates 21 C.F.R. § 1.21(a), a separate FDA regulation, because it does not disclose that “the aspartame in Diet Coke can lead to weight gain” is unavailing for similar reasons. (Compl. ¶ 45) Section 1.21(a), like 21 U.S.C. § 343(a), is a catch-all provision against misleading labels, and provides that a food label may be unlawful “if it fails to reveal facts that are ... [m]aterial in light of other representations” on the label, or otherwise “[m]aterial with respect to consequences which may result from use.” But both Section 343(r)(2)(D) and Section 105.66 enumerate what “material” facts must be disclosed alongside a “diet” claim: a soft drink bearing such a claim must contain a “low calorie” or “reduced calorie” disclosure, as Diet Coke does. *See* 21 U.S.C. § 343(r)(2)(D); 21 C.F.R. § 105.66(e). Because the FDCA and its implementing regulations permit the term “diet” and specify the disclosures that must accompany it, the general language of Section 1.21(a) cannot be used to impose **additional** disclosure requirements. *See Gustavson v. Wrigley Sales Co.*, 2014 U.S. Dist. LEXIS 1693, at *30 (N.D. Cal. Jan. 7, 2014) (holding that the absence of a disclosure alongside a claim that the FDCA “expressly allow[s]” cannot “possibly be an actionable omission under Section 1.21”). Plaintiffs’ attempt to impose such a requirement is therefore preempted.⁷

⁷ In any event, Congress has specified what disclosures are necessary regarding health risks in connection with nutrient content claims, and has exempted pre-1989 soft drinks from those requirements, instead subjecting them to the requirements of Section 343(r)(2)(D). *See* 21 U.S.C. § 343(r)(2)(B) (specifying disclosures that are required when a food contains a nutrient at a level that increases health risks); § 343(r)(2)(D) (providing that those disclosure requirements

II. PLAINTIFFS' GBL CLAIMS ARE BARRED BY THE STATUTES' SAFE HARBOR PROVISIONS

Plaintiffs' challenge to Diet Coke's FDCA-compliant brand name under NY GBL §§ 349-350 is not only expressly preempted, but also barred by latter statute's "safe harbor" clauses, which provide a "complete defense" to claims challenging conduct or advertising that is "subject to and complies with the rules and regulations" of any federal agency, including FDA. N.Y. Gen. Bus. L. §§ 349(d); 350-d.⁸ These provisions mandate dismissal of any complaint that, like this one, arises from an FDCA-authorized food label. *See Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144 (S.D.N.Y. 1987) (determining that compliance with FDA regulations governing over-the-counter warning requirements was a "complete defense" to Section 349 and Section 350 claims); *Flagg v. Yonkers S&L Ass'n*, 307 F. Supp. 2d 565, 581 n.19 (S.D.N.Y. 2004) ("[C]ompliance with applicable federal regulations is a complete defense to claims of deceptive business practices under § 349(d).").

III. PLAINTIFFS FAIL TO STATE A PLAUSIBLE CLAIM OF DECEPTION

Even if Plaintiffs' consumer protection claims were not preempted and barred by the safe harbor doctrine, the Court should dismiss them, as the *Becerra* court did, for failure to plausibly allege that Diet Coke's brand name is misleading to reasonable consumers. *See Becerra*, 2018 U.S. Dist. LEXIS 31870, at *8.

Plaintiffs claim that Coca-Cola's mere use of the word "diet" in the brand name Diet Coke misled them by causing them to believe that the product "would contribute to healthy

"do[] not apply" to diet soft drinks). By seeking a disclosure that Diet Coke "leads to weight gain," Plaintiffs are attempting to impose just such a requirement.

⁸ Although the "safe harbor" provision of Section 350-d is limited by its terms to rules and regulations administered by the Federal Trade Commission, "[c]ourts have construed § 350-d to be congruent with § 349(d) and also to cover regulations promulgated by federal agencies other than the FTC." *Marcus v. AT&T Corp.*, 938 F. Supp. 1158, 1173 (S.D.N.Y. 1996).

weight management,” when in fact epidemiological studies suggest a link between artificial sweetener consumption and weight gain. (Compl. ¶¶ 49, 51) This claim of deception is implausible for two reasons. First, Plaintiffs have failed to plausibly allege that the brand name “Diet Coke” conveys *any* message about the product’s “contribut[ion] to healthy weight management,” or, indeed, any message at all other than that the product is low in calories. Second, the studies and articles that Plaintiffs rely upon do not support their conclusion that the artificial sweeteners in Diet Coke undermine “healthy weight management,” and many explicitly disclaim any such conclusion.

A. Reasonable Consumers Do Not Believe That Diet Coke’s Label Makes a Promise That Drinking Diet Coke Will Cause Weight Loss

To survive this motion to dismiss, Plaintiffs must plausibly allege that the brand name Diet Coke would be “materially deceptive or misleading ‘to a reasonable consumer acting reasonably under the circumstances.’” *Goldemberg v. Johnson & Johnson Consumer Cos.*, 8 F. Supp. 3d 467, 478 (S.D.N.Y. 2014) (quoting *Oswego Laborers’ Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 26 (N.Y. 1995)). Plaintiffs must demonstrate “more than a mere possibility that [the defendant’s] label might conceivably be misunderstood by some few consumers viewing it in an unreasonable manner.” *Ebner v. Fresh, Inc.*, 818 F.3d 799, 806 (9th Cir. 2016).⁹ Rather, they must credibly allege that the label at issue was “‘likely to mislead [or deceive] a reasonable consumer acting reasonably under the circumstances,’” *i.e.*, “deception must be probable, not just possible.” *Fermin v. Pfizer Inc.*, 215 F. Supp. 3d 209, 211 (E.D.N.Y. 2016) (emphasis added). Whether a plaintiff’s allegations suffice for this purpose is a question

⁹ Because California consumer protection law applies “the same reasonable consumer test” as New York law, “California’s ‘reasonable consumer’ inquiry can properly inform New York’s.” *Kacocha v. Nestle Purina Petcare Co.*, 2016 U.S. Dist. LEXIS 107097, at *54 n.22 (S.D.N.Y. Aug. 11, 2016).

of law: “[I]t is well settled that a court may determine as a matter of law that an allegedly deceptive advertisement would not have misled a reasonable consumer.” *Fink v. Time Warner Cable*, 714 F.3d 739, 741 (2d Cir. 2013).

Here, Plaintiffs’ core allegation—that consumers interpret the common brand name “Diet Coke” to convey that the product is scientifically linked to “weight management”—does not meet this exacting standard. As the *Becerra* court held, reasonable consumers understand “diet” on Diet Coke to mean “that [it] merely deletes the calories usually present in regular Coke.” *Becerra*, 2018 U.S. Dist. LEXIS 31870, at *8. Dictionaries confirm this meaning of “diet” as “low calorie,” even identifying low calorie soft drinks as the quintessential context for the term. *See, e.g.*, Diet (adj.), *Merriam-Webster’s Collegiate Dictionary* (11th ed.) (“1: reduced in or free from calories <a diet soft drink>”); Diet (adj.), *The American Heritage Dictionary of the English Language* (5th ed.) (“2a. Having fewer calories. b. Sweetened with a non-caloric sugar substitute.”); Diet, *New Oxford American Dictionary* (3d ed.) (“[as modifier] (of food or drink) with reduced fat or sugar content: diet soft drinks”). FDA has codified that definition, classifying “diet” as a term “suggesting usefulness as [a] low calorie or reduced calorie food[.]” 21 C.F.R. § 105.66(e). And even the studies that Plaintiffs rely upon use the term “diet soft drink” to refer to “a low calorie soft drink,” as opposed to “a soft drink that is correlated with weight management.”¹⁰ Plaintiffs do not dispute that Diet Coke satisfies this universally-recognized definition of a “diet” soft drink, so they cannot plausibly allege that its brand name is

¹⁰ *See* Sharon Fowler et al., *Diet soda intake is associated with long-term increases in waist circumference in a biethnic cohort of older adults: The San Antonio Longitudinal Study of Aging*, 63 J. of the Am. Geriatrics Society 708, 711 (2015) (evaluating “relationship between increasing **diet soda** intake and escalating abdominal obesity”) (emphasis added) (cited at Compl. ¶ 23 n.6); Catherine S. Berkey et al., *Sugar-Added Beverages and Adolescent Weight Change*, 12 Obesity Research 778, 781 (2004) (evaluating beverage consumption behavior and noting that “**diet soda** intakes were not associated with higher total energy intakes”) (emphasis added) (cited at Compl. ¶ 26 n.8).

misleading to a reasonable consumer.

Plaintiffs also do not identify any other conduct by Coca-Cola that made or implied a broader message of “weight management” in connection with Diet Coke. They do not dispute that, as the *Becerra* court emphasized, “in supermarkets, Diet Coke is displayed next to regular soft drinks and is not sold in the health-food section.” *Becerra*, 2018 U.S. Dist. LEXIS 31870 at *8. Though they contend that artificial sweeteners are correlated with weight gain, they do not allege that Coca-Cola has ever concealed the use of artificial sweetener in Diet Coke, nor do they dispute that the use of artificial sweetener in diet soft drinks is widely known among consumers. *See Viggiano v. Hansen Natural Corp.*, 944 F. Supp. 2d 877 (C.D. Cal. 2013) (holding that “the fact that the soda is clearly labeled ‘diet’ **indicates to consumers that it contains artificial sweeteners; it is the lack of real sugar that renders a soda ‘diet’**”) (emphasis added). And finally, they do not dispute that “weight management” is a complex and individualized pursuit in which diet soda plays, at most, a modest role. Accordingly, “a reasonable consumer would simply not look at the brand name Diet Coke and assume that consuming it, absent any lifestyle change, would lead to weight loss.” *Becerra*, 2018 U.S. Dist. LEXIS 31870, at *9; *see also Nathan v. Vitamin Shoppe, Inc.*, 2018 U.S. Dist. LEXIS 22843 (S.D. Cal. Feb. 12, 2018) (rejecting plaintiff’s effort to impute a “weight loss” message to a product that merely promoted “weight management” and “appetite control.”).

Thus, even assuming that Plaintiffs sincerely believed that Diet Coke would assist with “weight management,” they cannot hold Coca-Cola accountable for this idiosyncratic interpretation. A reasonable consumer would interpret the brand name Diet Coke to merely communicate the truthful message that the product is free from calories—not that it “promotes weight management” for all who consume it. Because Plaintiffs have not plausibly alleged that a

reasonable consumer would be misled by Diet Coke's brand name, their complaint must be dismissed.

B. The Studies Relied Upon by Plaintiffs Do Not Support Their Theory of Deception

Even if Plaintiffs could allege that reasonable consumers understood the brand name "Diet Coke" to communicate a promise of weight management, their complaint would still fail because they have not plausibly alleged that that message was false. Although Plaintiffs cite to a number of studies and articles which they claim establish that diet soda "is likely to cause weight gain," the cited studies explicitly disclaim any such conclusion. (Compl. ¶ 17) Rather, as the *Becerra* court observed, even viewed "in the light most favorable to [Plaintiff], these studies all acknowledge that the question of *causation*, rather than *correlation* [between artificial sweetener consumption and weight gain], remains undetermined." *Becerra*, 2018 U.S. Dist. LEXIS 31870, at * 9.

Indeed, many of the studies express skepticism of a causal connection between consumption of artificial sweeteners and weight gain:

- "[C]ausality is far from established with regard to artificial sweetener use and weight gain At the current time, ***the jury remains out regarding a possible role of increased artificial sweetener use in the obesity and diabetes epidemics.***" Rebecca J. Brown et al., *Artificial Sweeteners: A Systematic Review of Metabolic Effects in Youth*, Int'l J. of Ped. 5 Int'l J. of Ped. Obesity 305, 309 (Aug. 2010) (cited at Compl. ¶ 19 n.2); see Metcalf Decl. Ex. 3.
- "***Whether [diet soda intake] exacerbated the [waist circumference] gains observed in [study] participants is unclear*** participants' decisions to use [artificial sweeteners] may have been driven by other factors—including family history and/or perceived personal weight-gain/health-risk trajectories—which increased [change in waist circumference], yet were not captured in our analyses." Sharon Fowler et al., *Diet soda intake is associated with long-term increases in waist circumference in a biethnic cohort of older adults: The San Antonio Longitudinal Study of Aging*, 63 J. of the Am. Geriatrics Society 708, 711 (2015) (cited at Compl. ¶ 23 n.6); see Metcalf Decl. Ex. 6.

- “Overall there was **limited evidence for the effect of nonnutritive sweeteners on BMI.**” Meghan B. Azad et al., *Nonnutritive sweeteners and cardiometabolic health: a systematic review and meta-analysis of randomized controlled trials and prospective cohort studies*, Can. Med. Ass’n J., Vol. 189, No. 28, 929-39 (July 2017) (cited at Compl. ¶ 28 n.10); see Metcalf Decl. Ex. 5.
- “**There may be no causal relationship between [artificial sweetener] use and weight gain.**” Sharon P. Fowler et al., *Fueling the Obesity Epidemic? Artificially Sweetened Beverage Use and Long-Term Weight Gain*, 16 Obesity 1894 (Aug. 2008) (cited at Compl. ¶ 25 n.7); see Metcalf Decl. Ex. 2.
- “[I]ntervention trials **consistently fail to document that [artificial sweeteners] promote weight gain, and observational studies provide only equivocal evidence that they might.**” Richard D. Mattes et al., *Nonnutritive Sweetener Consumption in Humans: Effects on Appetite and Food Intake and Their Putative Mechanisms*, 89 Am. J. Clin. Nutr. 1, 5 (Jan. 2009) (cited at Compl. ¶ 18 n.1); see Metcalf Decl. Ex. 4.
- “[T]hese observational data cannot establish causality ... [T]he ideal design, one that is randomized and longterm, is notably lacking.” Jennifer Nettleton et al., *Diet Soda Intake and Risk of Incident Metabolic Syndrome and Type 2 Diabetes in Multi-Ethnic Study of Artherosclerosis (MESA)*, 32 Diabetes Care 688, 692 (2009) (cited at Compl. ¶ 29 n.12); see Metcalf Decl. Ex. 7.

Thus, even if “reasonable consumers” interpret Diet Coke’s brand name to convey a message regarding weight management, Plaintiffs’ allegations establish that it is, at most, “unclear” whether that message is accurate. This further dooms their effort to establish that Diet Coke’s brand name is misleading to a reasonable consumer. See *Fink*, 714 F.3d at 742 (holding that plaintiffs’ claims “lack the facial plausibility necessary to survive a motion to dismiss” where “the allegations of the Complaint are materially inconsistent with the sole advertisement Plaintiffs have submitted” to the court); *Kardovich v. Pfizer, Inc.*, 97 F. Supp. 3d 131 (E.D.N.Y. 2015) (dismissing complaint due to “mismatches” between plaintiff’s allegations and studies relied upon in support); *Alamilla v. Hain Celestial Grp., Inc.*, 30 F. Supp. 3d 943, 944 (N.D. Cal. 2014) (dismissing complaint because articles incorporated by reference into the complaint “contradict the allegation upon which [plaintiffs’] entire complaint hinges”).

IV. PLAINTIFFS LACK STANDING TO PURSUE A CLAIM FOR INJUNCTIVE RELIEF

Because Plaintiffs do not and cannot allege that Coca-Cola's purported misconduct is causing them any continuing injury, their claims for injunctive relief should also be dismissed for lack of standing. A plaintiff seeking an injunction must demonstrate "continuing, present adverse effects" of the challenged conduct, such that, absent an injunction, "she is likely to be harmed again in the future in a similar way." *Buonasera v. Honest Co.*, 208 F. Supp. 3d 555, 564 (S.D.N.Y. 2016).

Plaintiffs can make no such showing here. Their sole purported "injury" is that Diet Coke's brand name misled them to "believe[] . . . that it would contribute to healthy weight management," when in fact there is "strong evidence that aspartame causes weight gain." (Compl. ¶¶ 48-49, 91) Even assuming these allegations are true, however, there is no risk of that injury recurring, because the presence of aspartame is already disclosed on Diet Coke's label. If Plaintiffs wish to avoid consuming it in the future, they have all the information they need in order to do so. They accordingly lack standing to pursue an injunction against Diet Coke's allegedly misleading labeling. *See Bernardino v. Barnes & Noble Booksellers, Inc.*, 2017 U.S. Dist. LEXIS 129038, at *16 (S.D.N.Y. Aug. 11, 2017) (no standing where plaintiff "concedes that her own conduct can prevent future harm"); *Elkind v. Revlon Consumer Prods. Corp.*, 2015 U.S. Dist. LEXIS 63464, at *8 (E.D.N.Y. May 14, 2015) ("Plaintiffs are now aware of the alleged misrepresentations that they challenge, so there is no danger that they will again be deceived by them.").

V. ALL OF PLAINTIFFS' COMMON LAW CLAIMS FAIL AS A MATTER OF LAW

Even if Plaintiffs' common law claims (Counts III-VIII) were not expressly preempted—which they are—they should each independently be dismissed for failure to state a claim.

A. Plaintiffs' Negligent Misrepresentation Claim Fails For Failure to Allege the Existence of a Special Relationship with Coca-Cola

As this Court has held, under New York law, “a claim for negligent misrepresentation lies only where there is a special duty of care,” *i.e.*, something “more than a normal commercial relationship.” *Rogers v. HSN Direct Joint Venture*, 1999 U.S. Dist. LEXIS 12111, at *7 (S.D.N.Y. Aug. 5, 1999) (Stanton, *J.*) (dismissing negligent misrepresentation claim for failure to show the existence of a special relationship). “In the commercial context, a closer degree of trust between the parties than that of the ordinary buyer and seller is required to establish the ‘existence of . . . a special relationship.’” *Izquierdo v. Mondelez Int’l, Inc.*, 2016 U.S. Dist. LEXIS 149795, at *20 (S.D.N.Y. Oct. 26, 2016) (quoting *Kimmell v. Schaefer*, 89 N.Y.2d 257, 263 (N.Y. 1996)).

Plaintiffs have plainly failed to allege the existence of any such “special relationship” beyond the relationship of “ordinary buyer and seller.” *Id.* Their negligent misrepresentation claim must therefore be dismissed.

B. Plaintiffs' Intentional Misrepresentation Claim Fails For Failure to Allege Intent to Defraud and Reasonable Reliance

Claims sounding in fraud, such as intentional misrepresentation, “are subject to the heightened pleading standards of Fed. R. Civ. P. 9(b), which requires that averments of fraud be ‘state[d] with particularity.’” *Cohen v. S.A.C. Trading Corp.*, 711 F.3d 353, 359 (2d Cir. 2013). To satisfy this requirement, a plaintiff must “plead those events which give rise to a strong inference that the defendant[] had an intent to defraud” and “knowledge of the falsity.” *Id.* Plaintiffs’ sole allegation in this regard is that Coca-Cola falsely promoted Diet Coke as a “diet” soft drink because “this representation is the major driver of Diet Coke sales.” (Compl. ¶ 39) An assertion such as this is legally insufficient to show an intent to defraud. *See In re Frito-Lay N. Am., Inc.*, 2013 U.S. Dist. LEXIS 123824, at *79 (E.D.N.Y. Aug 29, 2013) (rejecting

suggestion that a “desire[] to increase sales and revenue” was sufficient to support fraud claim because a “generalized motive to satisfy consumers’ desires [and] increase sales and profits ... does not support a strong inference of fraudulent intent”); *Landesbank Baden-Wuerttemberg v. Goldman, Sachs & Co.*, 478 F. App’x 679, 681 (2d Cir. 2004) (a “general profit motive common to all corporations ... does not suffice” to show motive for committing fraud).

In addition, Plaintiffs’ allegation that evidence showing a link between aspartame and weight gain “has been in the published (sic) and in the public domain, and recounted in major news outlets” defeats any effort to plead reasonable reliance, another element of an intentional misrepresentation claim. (Compl. ¶ 38) Courts have “repeatedly rejected claims of justifiable reliance where the representation relates to matters not peculiarly within the Defendant’s knowledge.” *Siegel v. Ford*, 2017 U.S. Dist. LEXIS 150147, at *24-25 (S.D.N.Y. Sep. 15, 2017); *see also Foxley v. Sotheby’s Inc.*, 893 F. Supp. 1224, 1230 (S.D.N.Y. 1995) (because alleged misrepresentation was “in the public domain,” it “cannot serve as the basis for a fraud cause of action”). Plaintiffs’ admission that the alleged misrepresentation has been “published” and is “in the public domain” thus precludes their claim for intentional misrepresentation.

C. Plaintiffs’ Breach of Express Warranty Claim Fails for Failure to Allege That They Gave Coca-Cola Pre-Suit Notice

Under New York law, “the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy.” *In re Frito-Lay N. Am., Inc.*, 2013 U.S. Dist. LEXIS 123824, at *86 (E.D.N.Y. Aug. 29, 2013). Though Plaintiffs allege in conclusory fashion that they “gave Coca-Cola notice of the breach before filing or asserting the claim” (Compl. ¶¶ 117, 124), allegations such as this, which merely parrot an element of a cause of action, are conclusory and need not be credited. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 548 (U.S. 2007) (“[A] formulaic recitation of a cause of

action's elements will not do.”). Because Plaintiffs fail to adequately allege notice, their breach of express warranty claim must be dismissed. *See Hubbard v. GMC*, 1996 U.S. Dist. LEXIS 6974, at *13 (S.D.N.Y. May 22, 1996) (dismissing breach of warranty claims where the complaint “lack[ed] any allegation that plaintiff notified [the defendant] . . . of the claimed defect.”).

D. Plaintiffs’ Claims for Breach of the Implied Warranties of Merchantability and Fitness Fail For Failure to Allege that Diet Coke Is Unfit For Human Consumption and For Failure to Allege Privity

Plaintiffs’ claims for breach of the implied warranties of merchantability and fitness fail for two separate reasons, each of which requires dismissal of these claims.

First, in this context, a claim for breach of either implied warranty requires an allegation that the food was unfit for human consumption. The implied warranty of merchantability “does not mean that the product will fulfill a ‘buyer’s every expectation’ but simply ‘provides for a minimum level of quality.’ Where the sale of a food or beverage is concerned, courts have ruled that the product need only be fit for human consumption to be of merchantable quality.” *Silva v. Smucker Natural Foods, Inc.*, 2015 U.S. Dist. LEXIS 122186, at *28-29 (E.D.N.Y. Sept. 14, 2015); *see also Donahue v. Ferolito, Vultaggio & Sons*, 786 N.Y.S.2d 153, 155 (1st Dep’t 2004) (breach of implied warranty of merchantability claim properly dismissed “on the ground that these merchantable beverages caused no ill effects and were fit for their intended purpose, namely, *liquid refreshment*”) (emphasis added). Similarly, a “warranty of fitness for ordinary purposes does not mean that the product will fulfill [a] buyer’s every expectation. Rather, it has been observed, such a warranty provides for a minimal level of quality.” *Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 258 n.4 (N.Y. 1995); *Atik v. Welch Foods, Inc.*, 2016 U.S. Dist. LEXIS 106497, at *40 (E.D.N.Y. Aug. 5, 2016) (the “implied warranty of fitness merely requires that

food be reasonably fit for human consumption.”) (internal quotation marks omitted).

Here, Plaintiffs have alleged only that Diet Coke may “lead[] to weight gain”—a charge that could be made of most food products sold in the United States. (Compl. ¶ 2) And their allegation that they would consider purchasing Diet Coke in the future if the product were “properly labeled” belies any suggestion that it is unfit for human consumption. (Compl. ¶ 59) Even if Plaintiffs had alleged that aspartame was unfit for human consumption, such an allegation would lack plausibility in light of FDA regulations endorsing aspartame’s safety. *See* 21 C.F.R. § 172.804 (“[A]spartame may be safely used in food ...”).¹¹ Thus, even assuming that Diet Coke failed to satisfy Plaintiffs’ expectations, they have not alleged and cannot allege that Coca-Cola breached the implied warranties of merchantability or fitness.

Second, “absent privity of contract, a purchaser cannot recover mere economic loss against a manufacturer under a theory of breach of implied warranty.” *Inter Impex S.A.E. v. Comtrade Corp.*, 2004 U.S. Dist. LEXIS 24431, at *15 (S.D.N.Y. Dec. 2, 2014). Plaintiffs allege that they purchased Diet Coke at convenience stores, not from Coca-Cola. (Compl. ¶¶ 48, 50) This requires dismissal of their breach of implied warranty claims. *See Tomasino v. Estee Lauder Cos.*, 44 F. Supp. 3d 251, 262 (E.D.N.Y. Aug. 26, 2014) (dismissing implied warranty claim for lack of privity where plaintiff “does not allege that she purchased the products from [defendant] or that she suffered personal injury”).

¹¹ *See also Additional Information about High-Intensity Sweeteners Permitted for use in Food in the United States*, www.FDA.GOV (“Aspartame is one of the most exhaustively studied substances in the human food supply, with more than 100 studies supporting its safety.”), available at <https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm397725.htm>.

E. Plaintiffs' Claim for Restitution Fails Because It Is Duplicative of Plaintiffs' Other Claims

Finally, Plaintiffs' claim for "restitution" must be dismissed as duplicative of Plaintiffs' other claims. Even accepting that restitution may be alleged as an independent cause of action (as opposed to a remedy sought), claims sounding in unjust enrichment are routinely dismissed as duplicative where they do not provide an independent basis for relief, but merely rise and fall with a plaintiff's other claims. *See Koenig v. Boulder Brands, Inc.*, 995 F. Supp. 2d 274, 290-91 (S.D.N.Y. 2014) ("[T]o the extent that Plaintiffs' other claims succeed, the unjust enrichment claim is duplicative, and if plaintiffs' other claims are defective, an unjust enrichment claim cannot remedy the defects."); *Bautista v. Cytosport, Inc.*, 223 F. Supp. 3d 182, 194 (S.D.N.Y. 2016) ("Courts will routinely dismiss an unjust enrichment claim that simply duplicates, or replaces, a conventional contract or tort claim."). Here, there is no independent basis for Plaintiffs' claim for "restitution."

CONCLUSION

Plaintiffs seek to impose requirements for the labeling of "diet" soft drinks that differ from those imposed by federal law, displacing the standards that have governed Diet Coke and countless other low calorie soft drinks for decades. Their claims are therefore preempted. In addition, Plaintiffs do not and cannot allege that Diet Coke's brand name is misleading to a reasonable consumer. Finally, they lack standing to pursue injunctive relief and cannot state a claim for any of their common-law causes of action. The complaint should be dismissed in its entirety. Because the deficiencies are not curable, the dismissal should be with prejudice and without leave to amend.

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